

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

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GILEAD SCIENCES, INC. and  
EMORY UNIVERSITY,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.  
and TEVA PHARMACEUTICAL  
INDUSTRIES, LTD.,

Defendants.  
-----X

Civil Action No.: 08-CV-10838 (RJS) (AJP)

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~~GILEAD SCIENCES, INC. and  
EMORY UNIVERSITY,~~

~~Plaintiffs,~~

~~v.~~

~~TEVA PHARMACEUTICALS USA, INC.  
and TEVA PHARMACEUTICAL  
INDUSTRIES, LTD.,~~

~~Defendants.~~  
-----X

~~Civil Action No.: 10-CV-1798 (RJS) (AJP)~~

**PROPOSED REVISED CASE  
MANAGEMENT PLAN AND  
SCHEDULING ORDER**

ECF

RICHARD J. SULLIVAN, District Judge:

This Revised Case Management Plan and Scheduling Order was adopted in accordance with Rules 16-26(f) of the Federal Rules of Civil Procedure.

Plaintiffs note the following:

(a) The discovery dates in the schedule were proposed by Defendants. Plaintiffs originally notified Defendants that it was unable to accept the schedule proposed, because it provided insufficient time between the close of all discovery (August 24, 2012, at the latest) and the close of the FDA's 30-month stay of approval concerning Defendants' generic Truvada® product (late July 2012). Thus, under Defendants' proposed schedule, Defendants potentially would have been permitted to launch a generic version of Truvada® before the Court had the opportunity to rule on the merits of this case or before Plaintiffs had sufficient time to move for a preliminary injunction. Such a scenario would unfairly prejudice Plaintiffs' statutorily safeguarded interests. Defendants, however, subsequently have notified Plaintiffs that Defendants would not launch a generic version of Truvada® until a date certain (May 1, 2013) or other triggering events, as described further below. Further, Defendants have stated that they will

provide a 60-day notice before they launch a generic version of Truvada®, as described further below. In view of the foregoing, Plaintiffs agree with the entry of the schedule below.

(b) Section 1112 of Subtitle B ("Federal Trade Commission Review") of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that brandname drug manufacturers and generic drug applicants file certain agreements with the Federal Trade Commission and the Assistant Attorney General within 10 business days of execution of the agreement. While the entry of this Case Management Plan and Scheduling Order may fall outside of the foregoing requirement, out of an abundance of caution, Plaintiffs intend to submit this Case Management Plan and Scheduling Order to the Federal Trade Commission and Assistant Attorney General within 10 business days. Defendants will also file the schedule with the Federal Trade Commission and the Assistant Attorney General. Plaintiffs or Defendants, if required, will seek modification of the Case Management Plan and Scheduling Order if the Federal Trade Commission and/or Assistant Attorney General object, comment or otherwise respond in such a way that Plaintiffs or Defendants conclude that entry of the Case Management Plan and Scheduling Order poses an unreasonable risk to Plaintiffs or Defendants.

**REVISED CASE MANAGEMENT PLAN AND SCHEDULING ORDER**

1. All parties do not consent to disposition of this case by a Magistrate Judge, pursuant to 28 U.S.C. § 636(c).
2. This case is not to be tried to a jury. However, if circumstances change, such as Defendants enter the market with their proposed product(s) prior to the expiration of the patents-in-suit, or any later date of exclusivity to which Plaintiffs are or become entitled, Plaintiffs reserve their right to request a jury.
3. No additional parties may be joined except with leave of the Court.
4. Amended pleadings may not be filed except with leave of the Court.
5. Initial disclosures related to the 08-cv-10838 lawsuit have been exchanged. Initial disclosures related to the claims and defenses associated with the 10-cv-1798 lawsuit pursuant to Rule 26(a)(1) will be completed not later than July 23, 2010.
6. All fact discovery is to be completed no later than:
  - a. December 31, 2010 of Emory University; and
  - b. September 2, 2011 of parties other than those identified in Paragraph 6(a).
7. The parties are to conduct discovery in accordance with the Federal Rules of Civil Procedure and the Local Rules of the Southern District of New York. The following interim deadlines may be extended by the parties on consent without application to the Court, provided the parties meet the fact discovery completion date in ¶ 6 above:

- a. Initial requests for production of documents, if any, for the claims and defenses associated with the 10-cv-1798 lawsuit are to be served by July 23, 2010.
  - b. Initial interrogatories, if any, for the claims and defenses associated with the 10-cv-1798 lawsuit are to be served by July 23, 2010. No interrogatories are to be served later than August 3, 2011. No interrogatories are to be served on Emory University later than November 19, 2010.
  - c. Depositions are to be completed by September 2, 2011. Depositions of Emory University and its current employees are to be completed by December 31, 2010.
    - i. Unless the parties agree or the Court so orders, depositions are not to be held until all parties have responded to initial requests for document production.
    - ii. There is no priority in deposition by reason of a party's status as plaintiff or defendant.
    - iii. Unless the parties agree or the Court so orders, non-party depositions (with the exception of former employees of Emory University) shall follow initial party depositions.
  - d. Requests to Admit are to be served by August 3, 2011. Requests to admit are to be served on Emory University by November 19, 2010.
8. Claim construction disclosures and briefing are to be completed as follows:
- a. The parties will exchange proposed meanings of claim terms on September 9, 2011.
  - b. Following the exchange of proposed meanings of claim terms, the parties are to meet and confer to determine if the Court's assistance is necessary to resolve claim construction disputes. If claim construction is necessary, the parties shall notify the Court by September 16, 2011 and shall proceed with briefing as described in ¶ 8.c.
  - c. If the parties disagree as to the meaning of claim terms (see ¶ 8.b.), opening claim construction briefs are to be simultaneously served and filed on November 4, 2011; rebuttal claim construction briefs are to be simultaneously served and filed on December 16, 2011; and, if necessary, the Court will schedule a claim construction hearing.
9. All expert disclosures, including reports, production of underlying documents and depositions are to be completed as follows:
- a. ~~PLAINTIFFS' PROPOSAL~~ If there is no dispute concerning the meaning of claim terms (see ¶ 8.b.); opening expert reports on issues where the party bears the



burden of proof are due November 4, 2011; rebuttal expert reports are due December 16, 2011; and expert depositions are to be completed by April 6, 2012.

- a. ~~[DEFENDANTS' PROPOSAL]~~ If there is no dispute concerning the meaning of claim terms (see ¶ 8.b.); opening expert reports on issues where the party bears the burden of proof are due November 4, 2011; rebuttal expert reports are due December 16, 2011; reply expert reports are due February 3, 2012; and expert depositions are to be completed by April 6, 2012.
- b. ~~[PLAINTIFFS' PROPOSAL]~~ If the parties disagree as to the meaning of claim terms (see ¶ 8.b.); opening expert reports on issues where the party bears the burden of proof at trial are due March 16, 2012; rebuttal expert reports are due May 4, 2012; and expert depositions are to be completed by August 24, 2012.
- b. ~~[DEFENDANTS' PROPOSAL]~~ If the parties disagree as to the meaning of claim terms (see ¶ 8.b.); opening expert reports on issues where the party bears the burden of proof at trial are due March 16, 2012; rebuttal expert reports are due May 4, 2012; reply expert reports are due June 22, 2012 and expert depositions are to be completed by August 24, 2012.

- 10. All discovery is to be completed no later than:
  - a. April 6, 2012, if there is no dispute concerning the meaning of claim terms (see ¶ 8.b.).
  - b. August 24, 2012, if the parties disagree as to the meaning of claim terms (see ¶ 8.b.).
- 11. The parties are to promptly notify the Court that all discovery has been completed (see ¶ 10) within 48 hours of the completion of all discovery. The Court will schedule a post-discovery status conference within three weeks after being notified of the close of discovery.
- 12. Pre-motion letters regarding dispositive motions, if any, are to be submitted no later than two weeks prior to the post-discovery status conference date which is to be determined. In accord with this Court's Individual Rule 2.A, response letters thereto are to be submitted within three business days from service of the initial pre-motion letter.
- 13. All counsel must meet for at least one hour to discuss settlement not later than two weeks following the close of fact discovery (see ¶6).
- 14. The parties shall submit a Joint Pretrial Order prepared in accordance with the undersigned's Individual Practice Rule 3 and Rule 26(a)(3). If this action is to be tried before a jury, proposed voir dire, jury instructions, and a verdict form shall be filed with the Joint Pretrial Order. Counsel are required to meet and confer on jury instructions and verdict form in an effort to make an agreed upon submission.

15. The parties anticipate the need to enter into a revised Protective Order.
16. The parties have met and conferred and will continue to meet and confer regarding electronic discovery. Defendants have agreed not to object to Gilead Sciences, Inc. disposing of routine emails of field sales representatives and other documents of field sales representatives, including those previously preserved, as if in the normal course of business.
17. Parties have conferred and their present best estimate of the length of trial is two (2) weeks.
18. The parties agree that trial for this case should be scheduled to occur after the trials associated with the following cases (to the extent trials are necessary in these cases):
  - a. *Gilead Sciences, Inc. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, 10-CV-1796 (S.D.N.Y.) (RJS)(AJP); and
  - b. *Merck, Sharp & Dohme Corp. and Bristol-Myers Squibb Company v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, 10-cv-1851 (S.D.N.Y.) (RJS)(AJP).
19. Defendants respectfully request, to the extent that the Court's schedule permits, trial in this case take place after August 1, 2013. Plaintiffs do not oppose Defendants' request for trial in this case to take place after August 1, 2013, to the extent that the Court's schedule permits.
20. Defendants will not launch a generic version of Truvada® until the earlier of the following:
  - a. a district court decision in this case holding all asserted claims of the patents-in-suit invalid, not infringed, or unenforceable;
  - b. a decision from a district court holding all asserted claims of the patents-in-suit invalid or unenforceable;
  - c. entry into the market, in the United States, of a generic version of Truvada® (this does not include generic versions of Truvada® that have not been approved by the FDA to be marketed in the United States), including a generic version of Truvada® authorized or licensed by Gilead Sciences, Inc. to enter the United States market;
  - d. May 1, 2013; or
  - e. as otherwise agreed by the parties.
21. Defendants will provide Plaintiffs with 60 days written notice before Defendants intend to launch a generic version of Truvada®. Defendants' obligation to provide such notice for a generic version of Truvada® will expire if this Court issues a final judgment holding all

asserted claims of the patents-in-suit invalid, not infringed, or unenforceable and this Court issues a final judgment holding all asserted claims of the patents-in-suit in the *Gilead Sciences, Inc. v. Teva Pharmaceuticals USA, Inc., et al.* (10-CV-1796) case invalid, not infringed, or unenforceable, or upon the occurrence of an event described in Paragraphs 20(a), (b), (c), or (e).

22. Notwithstanding Paragraph 20, Plaintiffs will seek a preliminary injunction, if necessary.
23. If Defendants fail to reasonably cooperate in expediting the case, Plaintiffs, if necessary, will seek an extension of the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)
24. Plaintiffs or Defendants, if required, will seek modification of this Case Management Plan and Scheduling Order if the Federal Trade Commission and/or Assistant Attorney General object, comment or otherwise respond in such a way that Plaintiff or Defendants concludes that entry of this Case Management Plan and Scheduling Order poses an unreasonable risk to Plaintiffs or Defendants.

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**TO BE COMPLETED BY THE COURT:**

25. [Other directions to the parties:]

26. A status conference is scheduled for \_\_\_\_\_, 2010 at \_\_\_\_:\_\_\_\_ (a.m./p.m.).

SO ORDERED.

DATED: New York, New York

May 26, 2010

Richard J. Sullivan

RICHARD J. SULLIVAN  
UNITED STATES DISTRICT JUDGE